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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/951,690	10/16/97	HERRICK	R 5488.1313718

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QMQ31/1006

EXAMINER

NGUYEN, T

ART UNIT

PAPER NUMBER

3738

DATE MAILED:

10/06/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 08/951,690	Applicant(s) HERRICK
Examiner Tram Nguyen	Group Art Unit 3738

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- Claim(s) 1-32 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) 20-28 is/are allowed.
- Claim(s) 1-19 and 29-32 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on Oct 16, 1997 is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_.
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 252, as mentioned on page 45; element 276, as mentioned on page 46. Correction is required.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: elements 232 and 248, as illustrated in Figure 27. Correction is required.

***Specification***

3. The disclosure is objected to because of the following informalities:
  - a. Applicant has designated both "thin retaining lip" and "thin elongated lip" as being element 48. However, nowhere in the specification does applicant disclose that the thin retaining lip is analogous to the thin elongated lip. Therefore, the examiner does not know if applicant intends for these two terms to mean the same structure.
4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the disclosure fails to describe a "posterior edge" and "central edge" as recited in claims 2 and 3, or a "starter tip" as recited in claim 18.

Appropriate correction is required.

***Claim Objections***

5. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claim 2 depends upon claim 2 (i.e., refers back to itself). Therefore, by definition, claim 2 does not further limit the subject matter of a previous claim, or claim 1.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2-4 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, applicant has recited a "posterior edge" and "central edge" in claims 2 and 3, and a "starter tip" in claim 18. However, none of these limitations are mentioned or described in the disclosure. Therefore, the examiner does not understand how to interpret the metes and bounds of these claims insofar as they are described in terms not contained in the written disclosure.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4, 8, 12-19, and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 1 recites the limitation "the thin elongated tip" in line 5. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to recite a *thin elongated lip*?

b. Claim 2 depends upon itself, which makes the claim indefinite insofar as the examiner does not know how to determine the metes and bounds of the claim. Did applicant intend for claim 2 to depend upon *claim 1*? Claim 2 recites the limitation "said control axis" in line 3. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to recite *said central axis*?

c. In claim 3, applicant recites the limitation "its" in line 3. Applicant is reminded that the use of pronouns in citing a limitation constitutes improper claim language. Therefore, applicant should be careful not to use pronouns in this and any following claims.

d. Claims 8, 12, and 17 recite the limitation "the same", which limitation renders the claims indefinite insofar as the examiner is not always sure as to what the limitation refers.

e. Claim 18 recites the limitation "the thin elongated tip" in lines 6-7. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to recite a *thin elongated lip*?

- f. Claim 19 recites the limitation "the starting tip" in line 3. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to recite *the starter tip*?
- g. Claim 29 is indefinite because the claim recites the limitation "a said starting tip" in line 9. The limitation "a said" is unclear as providing double antecedents. Furthermore, claim 29 also recites the limitation "the thin elongated tip" in lines 15-16. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to recite a *thin elongated lip*?
- h. Claim 31 recites in line 12 a "thin retaining lip thin elongated lip", such limitation not making any grammatical sense. Did applicant intend to recite either a thin retaining lip, or a thin elongated lip? Furthermore, claim 31 also recites the limitation "the thin elongated tip" in lines 13-14. There is insufficient antecedent basis for this limitation in the claim. Did applicant intend to recite a *thin elongated lip*?

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Guena et al. (U.S. Patent No. 5,417,651) for the following reasons:

With respect to claims 1-4, see Figures 1 and 4 for a punctum plug (10) comprising an elongated member (2) having a thin elongated lip (3) which is positioned in a generally anterior

direction upon insertion in to a punctum opening, the thin elongated lip having a posterior edge which is positioned away from the cornea, the central axis being coaxial with the elongated axis of the elongated member, wherein one end is curved anteriorly relative to the thin elongated tip.

12. Claims 1-3, 5, and 18, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Seder et al. (U.S. Patent No. 4,959,048), for the following reason:

a. With respect to claims 1-3, see Figure 4 for a punctum plug (100) comprising an elongated member (106) having a thin elongated lip (104) which is positioned in a generally anterior direction upon insertion in to a punctum opening, the thin elongated lip having a posterior edge which is positioned away from the cornea, wherein one end is curved anteriorly relative to the thin elongated tip.

b. With respect to claim 5, see Figure 4 for a punctum plug (100) comprising an elongated member having at one end a lip (104), the elongated member having a portion curved anteriorly relative to the lip.

c. With respect to claim 18, see Figure 4 wherein the other end of the punctum plug includes a shaped distal tip (108).

13. Claims 29 and 31-32, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Herrick (U.S. Patent No. 5,163,959), for the following reasons:

a. With respect to claim 29, see Figure 1 and 10(b) for a punctum plug comprising an elongated member having a central member (22) with a predetermined cross-sectional dimension, the member having at one end a tip insertion section (26) having an offset (i.e., beveled or angled) distal starting tip (32), the offset distal starting tip having a smaller cross-section than the tip

insert section, and wherein the member has a second end which comprises a thin elongated lip (34).

b. With respect to claims 31 and 32, see Figures 10(a) through 10(d) for the method of treating a tear deficiency with the recited punctum plug.

### ***Double Patenting***

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1 and 4-17 are rejected under the judicially created doctrine of double patenting over claims 1-3, 13-15, 17, and 19-23 of U. S. Patent No. 5,723,005 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a punctum plug having a thin elongated lip at one end and a collapsible flared section at another. The end with the collapsible flared section also terminates in a tip insertion section, the insertion section including a distal starting tip. The elongated member is slightly curved, as is the thin elongated lip.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

#### ***Allowable Subject Matter***

16. Claims 20-28 are allowed.

17. The following is a statement of reasons for the indication of allowable subject matter:

The prior art fails to disclose a punctum plug having a tip insertion section which, after being inserted into the punctum opening, expands to a generally oval shape. The prior art also fails to disclose a punctum plug having an elongated, slightly curved member whose ends comprise a thin retaining lip and a tip insertion section having an offset distal starting tip.

18. Claims 19 and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No.'s 3,949, 750; 4,461,295; 4,660,546; 4,915,684; 5,049,142; 5,503,030; 5,171,270; 5,282,063; 5,318,513; 5,423,777; 5,466,258; and 5,437,625 all show various features of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tram Nguyen whose telephone number is (703) 308-0804. The examiner can normally be reached on Monday - Friday from 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached at (703) 308-2672. The fax phone number for this group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.

Tm  
TAN  
September 30, 1998

  
MICHAEL J. MILANO  
PRIMARY EXAMINER  
ART UNIT 3738